

Amendment and Response Under 37 C.F.R. 1.116

Applicant: David Francischelli et al.

Serial No.: 10/056,806

Filed: January 25, 2002

Docket No.: M190.135.101

Title: SYSTEM AND METHOD OF PERFORMING AN ELECTROSURGICAL PROCEDURE**REMARKS**

This Amendment is responsive to the Final Office Action mailed August 18, 2003. In that Office Action, claims 1-10, 19, 20, and 22-31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu et al., U.S. Patent No. 5,688,267 ("Panescu"). Claims 1-3, 33, 25-28, and 31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Whayne et al., U.S. Patent No. 5,853,411 ("Whayne"). Claims 2-11, 15, and 22-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Whayne. Claims 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Whayne and further in view of Mulier et al., U.S. Patent No. 5,897,553 ("Mulier"). Finally, claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Jackson et al., U.S. Patent No. 5,383,874 ("Jackson"), and Edwards, U.S. Patent No. 6,009,877 ("Edwards"). Claims 12-14 have been objected to as being dependent upon a rejected base claim. With this Response, claims 1, 22, and 28 have been amended. Claims 1-31 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. §§102 and 103

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu and as being anticipated by Whayne. Amended claim 1 relates to a method of making a lesion at living tissue at a target site. The method includes providing an electrosurgical system having an electrosurgical instrument with an electrode and a power source with multiple settings, determining a desired depth for the lesion, selecting a desired power setting, and applying electrical energy to the electrode in contact with the living tissue. The energy is applied to the living tissue for a recommended energization time period based upon the desired lesion depth and the selected power setting. The recommended energization time period is determined prior to the step of applying electrical energy to the electrode. The step of selecting a desired power setting is completed prior to determining the recommended energization time period. Such limitations are not taught or otherwise suggested by any of the cited references.

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In particular, Panescu relates to a method for sensing multiple temperature conditions during tissue ablation. The method of Panescu describes a physician pre-selecting a targeted ablation time, a maximum power setting, and a maximum temperature to achieve a desired lesion depth (column 11, lines 14-20). Based upon these physician selected parameters, the master controller 98 selects a fixed power level and controls the rate at which the electrode 16 is cooled to complete the ablation procedure within the pre-selected parameters (column 11, lines 27-35). As such, Panescu teaches using a pre-determined or pre-selected time period to identify the proper power setting for the subsequent ablation process. As such, the time period is determined prior to selection of a power setting. As argued in Applicant's Response to the Office Action mailed April 29, 2003, this teaching is the converse of the limitations of claim 1 in which the recommended energization time period is based upon the selected power setting. Further, in order to clarify claim 1 and to expedite examination, claim 1 has been amended to include the limitation that the step of selecting a desired power setting is completed prior to determining the recommended energization time period. Amended claim 1 clearly precludes use of a time period that is determined before selection of the desired power setting. As a result, Panescu fails to teach or otherwise suggest the limitations of amended claim 1.

Wayne also fails to teach or otherwise suggest the limitations of amended claim 1. As recited in Applicants' previous Response, Wayne describes temperature sensors on the electrode structure to determine the actual temperature of the electrode and/or of the surrounding tissue (column 25, lines 30-40). Wayne utilizes the temperatures sensed by the sensors to adjust the time and power level to achieve desired lesion patterns (column 25, lines 37-40). Therefore, Wayne teaches regulation of variable time and power levels based upon the temperatures sensed by the sensors. Otherwise stated, since the time varies during ablation depending upon temperature feedback, the time is not determined until well after ablation has begun. This is in direct contrast to the limitations of amended claim 1, which recites that the recommended energization time period is determined prior to the step of applying electrical energy to the electrode since ablation cannot begin until application of electrical energy to the electrode. Since Wayne teaches varying the ablation time during procedure, Wayne teaches against the limitation of amended claim 1. In addition, Wayne also teaches periodically

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adjusting the power setting based upon the sensed temperatures. Accordingly, Whayne teaches against the step of selecting a desired power setting prior to determining the recommended energization time period as also required by amended claim 1. As such, Whayne fails to teach or otherwise suggest the limitations of amended claim 1.

For at least the above-described reasons, none of the cited references teach or otherwise suggest the limitations of amended claim 1. Accordingly, Applicant believes claim 1 to be allowable.

Claims 2-10, 19, and 20 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu, and claims 2 and 3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Whayne. In addition, claims 2-11 and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Whayne. Each of claims 2-10, 19, and 20 depend from amended claim 1. As described above, Panescu and Whayne fail to teach or otherwise suggest the limitations of amended claim 1. As a result, dependent claims 2-10, 19, and 20 are similarly believed to be allowable over the cited references.

Claims 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu and Whayne and further in view of Mulier. Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Jackson and Edwards. Each of claims 16-18 and 21 depends from amended claim 1, which is believed to be allowable. Further, since Panescu and Mulier teach against the limitations of amended claim 1, Mulier, Jackson, and Edwards fail to alter the analysis. Consequently, dependent claims 16-18 and 21 are also believed to be allowable over the cited references.

Independent claim 22 was rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu and under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Whayne. Amended, independent claim 22 relates to an electrosurgical system for performing an electrosurgical procedure on living tissue. The system includes an electrosurgical instrument, a power source, and an energization look-up table. The power source has multiple available power settings and is electrically connected to the electrosurgical instrument. The energization look-up table corresponds with the electrosurgical instrument and includes a power setting data set, a lesion depth data set, and energization time period information organized as a dependent variable

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of the power setting and lesion depth data sets. The power setting data set includes at least one of the multiple available power settings of the power source. The energization look-up table is adapted to identify a recommended energization time period based upon a cross-reference of a selected power setting relative to the power setting data set in a desired lesion depth relative to the lesion depth data set. The power source is adapted to be set to the selected power setting throughout the recommended energization time period. Notably, the amendment does not present new matter. In particular, "function" is defined as "a variable (of a quality, trait, or measurement) that depends on and varies with another" (*Merriam-Webster's Collegiate Dictionary*, 10th Ed., p. 471). As such, replacing the term "function" with the term "dependent variable" merely clarifies the meaning of the original claim 22. For similar reasons as described with respect to claim 1, none of the cited references teach or otherwise suggest such limitations.

As described above, Panescu teaches determining a proper power setting based upon a pre-determined time period in direct contrast to the limitations of claim 22, which identifies a recommended energization time period based on a selected power setting. As fully described in Applicants' previous Response, Panescu teaches a lesion depth "D_{50c}" as being a function of the temperature "T_i" of the electrode, the electrode transmitted by the electrode and the time "t" the tissue is exposed to the electrode (column 9, lines 5-15). Panescu only teaches the relationship between these parameters as a depth "D_{50c}" function. Accordingly, looking to table 1 of Panescu, the information is organized with time as a constant rather than as a variable. This is in direct contrast to the limitations of amended claim 22, which recites an energization look-up table including energization time period information organized as a dependent variable of the power setting and lesion depth data sets. Moreover, although Panescu describes that other matrices can be developed for an array of values for time, Panescu does not describe a single energization look-up table including the energization time period information organized as a dependent variable of the power setting and lesion depth data set as required by amended claim 22. Therefore, Panescu fails to teach or otherwise suggest the limitations of amended claim 22.

Whayne fails to alter this analysis. As described above, Whayne teaches variable time and power levels rather than a recommended energization time period based on a selected power setting. Since the time and power levels are constantly varied based upon sensed temperatures,

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Whayne also fails to teach or otherwise suggest an energization look-up table including energization time period information organized as a dependent variable of the power setting and lesion depth data set. Rather, the tables of Whayne are organized as a function of lesion geometry or depth (Tables 1-4). As a result, the limitations of claim 22 are not taught or otherwise suggested by Whayne.

Due at least in part to the reasons described above, none of the cited references teach or otherwise suggest the limitations of amended, independent claim 22. As a result, amended claim 22 is believed to be allowable.

Claims 23-27 were rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu and under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Whayne. Claims 25-27 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Whayne. Each of claims 23-27 depend from amended, independent claim 22. As previously described, amended claim 22 is believed to be allowable over the cited references. Accordingly, dependent claims 23-27 are also believed to be allowable over the cited references.

Independent claim 28 was rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu and as being anticipated by Whayne. Independent claim 28 was also rejected under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Whayne. Amended, independent claim 28 relates to an electrosurgical system for performing an electrosurgical procedure. The system includes an electrosurgical instrument having an electrode at a distal portion, a power source electrically connected to the electrosurgical instrument for selectively energizing the electrode and having multiple available settings, and a means for electronically selecting a recommended energization time period by reference to a predetermined length of time information that relates to the electrosurgical instrument and based upon a selected power setting and a desired lesion depth. For similar reasons as described with respect to amended claims 1 and 22, none of the cited references teach or otherwise suggest the limitations of amended claim 28.

For example, Panescu teaches a physician pre-selecting a targeted ablation time, a maximum power, and a maximum temperature prior to beginning the electrosurgical procedure (column 11, lines 6-61). The physician inputs these values into the controller of Panescu, and

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the controller then selects a fixed power level in a temperature to be maintained by the cooling rate. As such, the ablation time is determined by the physician before the power level is ascertained. This is in direct contrast to the limitations of claim 28 which includes a controller for electronically selecting a recommended energization time period, since a physician manually selecting a time period does not electronically select that time period. The teachings of Panescu also are in contrast to the limitations of amended claim 28 reciting a means for electronically selecting a recommended energization time period based upon a power setting selected prior to energizing the electrode. Instead, as described above, Panescu teaches constantly varying the power setting based upon sensed temperatures during ablation. Furthermore, Wayne varies the time and power levels based upon the ablation temperatures rather than choosing the time based upon a power setting selected prior to energizing the electrode as recited in amended claim 28. As a result, Panescu and Wayne fail to teach or otherwise suggest the limitations of amended claim 28. Therefore, claim 28 is believed to be allowable.

Claims 29-31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Panescu and/or Wayne and under 35 U.S.C. § 103(a) as being unpatentable over Panescu in view of Wayne. Each of claims 29-31 depends from amended, independent claim 28. As described above, amended claim 28 is not taught or otherwise suggested by any of the cited references and is believed to be allowable. For at least these reasons, dependent claims 29-31 are also believed to be allowable.

CONCLUSION

In light of the above, Applicant believes independent claims 1, 22, and 28 and the claims depending therefrom, are in condition for allowance. Allowance of these claims is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 500471.

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The Examiner is invited to contact the Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response.

Respectfully submitted,

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By their attorneys,

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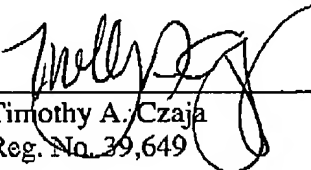
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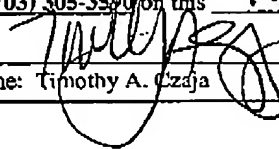
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The undersigned hereby certifies that this paper or papers, as described herein, are being transmitted via facsimile to the attention of Examiner Michael Peffley, at Facsimile No. (703) 305-3580 on this 14th day of October, 2003.

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